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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,033

07/11/2003

Yaron Keidar

50572/AW/W112

4112

23363 7590 03/17/2008
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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,033	Applicant(s) KEIDAR, YARON	
	Examiner Timothy J. Neal	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendments received on 10/01/2007 and the Request for Continued Examination received on 10/31/2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 18 are rejected under 35 U.S.C. 103(a) as being anticipated by Bonutti (US 5,814,073) in view of Klyce et al. (US 4,863,430).

Bonutti discloses:

1. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (54); and a dilating tip slidably mounted on the distal end of the tubular body (30) and comprising a segmented surface (Items 88, 90, 92, and 94) that is generally transverse to the axis of the tubular body, and a generally rigid tube extending distally from the segmented surface and having a sharp distal end adapted to puncture tissue (Column 3 Lines 56-67); wherein distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface to thereby open the segmented surface (Figs 1 and 2).

2. A device according to claim 1, wherein the elongated tube is generally cylindrical (54).

3. A device according to claim 1, where the segmented surface comprises two or more segments (88, 90, 92, and 94).

4. A device according to claim 1, where the segmented surface comprises three or more segments (88, 90, 92, and 94).

5. A device according to claim 1, wherein the dilating tip further comprises a ring mounted in surrounding relation to the tubular body (Fig 1).

6. A device according to claim 5, wherein the segmented surface comprises a plurality of segments, each of which is hingedly attached to the ring (Fig 2).

7. A device according to claim 1, wherein the dilating tip is generally funnel-shaped (Fig 1).

8. A device according to claim 1, wherein the generally rigid tube of the dilating tip is segmented (Fig 1).

18. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (54); a dilating tip slidably mounted on the distal end of the tubular body (30) and comprising: a ring mounted in surrounding relation to the distal end of the tubular body (proximal portion of Item 30); a segmented surface that is generally transverse to the axis of the tubular body, the segmented surface comprising three or more segments (88, 90, 92, and 94), each segment being hingedly attached to the ring (Fig 2); and a generally rigid tube extending distally from the segmented surface (Fig 1), the tube having a sharp distal end adapted to puncture tissue (Column 3 Lines 56-67) and being segmented into three or more segments (88, 90, 92, and 94); wherein distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface and the generally rigid tube to thereby open the segmented surface and the generally rigid tube (Figs 1 and 2).

Bonutti does not explicitly disclose the tubular body being flexible. Klyce teaches a flexible trocar to access a site where it is difficult to use a straight trocar (Column 1 Lines 35-52, Abstract, and Item 24). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonutti's rigid body to include Klyce's flexible body. Such a modification would allow the trocar to be used in areas where straight trocars present difficulties. The Examiner is citing additional references in the conclusion that include flexible trocars for similar purposes.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073 in view of Klyce '430 as applied to claim 1 as stated above.

Bonnuti discloses the invention substantially as claimed as stated above.

Bonnuti does not explicitly disclose the claimed lengths and diameters of the generally rigid tube of the dilating tip. However, the Examiner considers it within the purview of one having ordinary skill in the art to modify a device's length and diameter to meet the desired sizes for a given application. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's dimensions to include those of the claims. Such a modification would be necessary for the device to be used in certain applications.

Bonnuti also does not explicitly disclose the use of nitinol for the tip. However, the Examiner considers it to be old and well known in the art to use nitinol in a variety of applications because it is biocompatible. Bonnuti discloses the use of biologically compatible alloys for use with his invention (Paragraph 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's tip to include nitinol. Such a modification would provide a well-known alloy with desirable biocompatibility.

Claims 14-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073 in view Klyce '430 as applied to claim 1 and 18 stated above, and further in view of Wallace et al. (US 6,254,628).

Bonnuti discloses the invention substantially as claimed as stated above.

Bonnuti does not explicitly disclose a wire extending proximally from the dilating tip to near the proximal end of the tubular body to effect proximal movement of the dilating tip

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relative to the tubular body and a slidable member on the proximal end of the tubular body, the slidable member being connected to the wire so that proximal movement of the slidable member pulls the wire and causes the proximal movement of the dilating tip relative to the tubular body. Wallace teaches the concept of controlling the distal movement of a retractable or sliding element from the proximal end of the device (Fig 28-34). Wallace teaches a pull tab connected to a pull wire that is connected to a pulling control mechanism on the proximal end of the catheter (Col 18 Line 66 through Col 19 Line 3). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Bonnuti's device to include Wallace's pull wire and proximal member. Such a modification would allow the operator to manipulate the action of the distal tip from a location proximal to the tip, possibly outside the body.

Bonnuti and Wallace disclose the invention substantially as claimed. They do not disclose a latch for maintaining the position of the slidable member. However, the Examiner considers latches to be known for selectively maintaining the position of a wide variety of elements. Therefore, it would have been obvious to a person having ordinary skill in the art to modify Bonnuti and Wallace's device to include a latch mechanism for maintaining the position of the slidable member. Such a modification would prevent the tip from undesirably opening. It gives the operator control over the opening and closing of the distal tip. If the tip opens prematurely, damage will occur to the surrounding tissue.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073 in view of Klyce '430 as applied to claim 1 as stated above, and further in view of Devos et al. (US 6,099,511).

Bonnuti discloses the invention substantially as claimed as stated above. Bonnuti does not disclose a pressure valve at or near the proximal end of the tubular body. Devos teaches a pressure valve at or near the proximal end of the tubular body (Fig. 1 Item 30). Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's apparatus to include Devos's pressure valve. Such a modification would be to measure different pressures in a catheterized heart.

Response to Arguments

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has argued that Bonutti does not include a flexible body. The Examiner has included one rejection showing the obviousness of making a trocar flexible. More references are provided below as relevant art regarding flexible trocars.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Broadnax, Jr. (US 4,976,684), Synder (US 3,991,756), and Schneck et al. (US 4,553,542) all disclose flexible trocars.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731